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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,708	10/03/2003	Charlotte A. Kensil	8449-322-999	9606
20583	7590	10/21/2004	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			KIM, YUNSOO	
			ART UNIT	PAPER NUMBER
			1644	
DATE MAILED: 10/21/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/679,708	KENSIL ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Yunsoo Kim	1644	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10/3/03, 12/29/03 and 2/26/04.  
 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 46-65 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☒ Claim(s) 46-65 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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## DETAILED ACTION

### Amendments

1. Applicant's amendments, filed 10/3/03, 12/29/03 and 2/26/04 have been entered.

New Title has been entered.

Claims 1-45 have been canceled.

Claims 46-65 have been added.

Claims 46-65 are pending.

### Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 46-54 and 60-65 drawn to a method of enhancing the immune response to an antigen, classified in Class 424, subclass 184.1.
- II. Claims 55-59 drawn to a composition of excipient classified in Class 424, subclass 193.1

*Claims 55-59 are improper dependent claims because the independent Claim 46 is a method and not a composition claim.*

3. Groups II and I are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

Method of inducing immune response can be accomplished by products that differ in physicochemical structures than that set forth in Group II.

4. Because these inventions are distinct for the reason given above and have acquired a separate status in art as shown by their different classification and recognized divergent subject matter. Further, even though some cases the classification is shared, a different field search would be required based upon the structurally distinct products recited and the method of use. Moreover, prior art search also requires a literature search. It is undue burden for an examiner to search more than one invention. Therefore, restriction for examination purposes as indicated is proper.

### Species Election

5. This application contains claims directed to the following patentably distinct species of the claimed Groups I-II wherein:

*If one of Groups I-II is selected:* Applicant is further required to elect a particular form of the excipient from the following, (e.g. See Claims 46 and 55-61 and Specification p.10-11, overlapping paragraph, and p.16, 20 Tables 1, 4 and 5):

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- a.  $\beta$  cyclodextrin,
- b. human serum albumin,
- c. deacylsaponin,
- d. non-ionic surfactant,
- e. polyvinylpyrrolidone (Plasdone C15),
- f. aluminum hydroxide,
- g. agent with anesthetic action, or
- h. unmodified or derivative of cyclodextrin.

In addition to electing a specific form of an excipient (a)- (h), if Applicant elects non-ionic surfactant, Applicant is required to elect an ultimate species of non-ionic surfactant from the Specification (page 13) (e.g. (d) non-ionic surfactant (Polysorbate 20)).

These species are distinct because of their physicochemical properties and modes of action; thus each species represents patentably distinct matter.

Applicant is further required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

6. In addition to the election above in Section 5, this application contains claims directed to the following patentably distinct species of the claimed Groups I-II wherein:

*If one of Groups I-II is selected:* Applicant is further required to elect a particular antigen, from the following, (e.g. See Claim 54 and Specification p.11-12 overlapping paragraph):

- a. peptide,
- b. protein,
- c. polysaccharide,
- d. lipid,
- e. nucleic acid,
- f. virus, or
- g. bacteria.

In addition to electing a specific form of an antigen (a)- (g), if Applicant elects virus or bacteria, Applicant is required to elect an ultimate species of antigen from the Specification (pages 11-12) (e.g. (f) Virus (HIV)).

These species are distinct because of their physicochemical properties and modes of action; thus each species represents patentably distinct matter.

Applicant is further required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

7. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a). Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.


9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

#### Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yunsoo Kim  
Patent Examiner  
Technology Center 1600  
October 12, 2004

  
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10/14/04